



Art Unit: 1641

### EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

2.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Cahn on April 8, 2004 to cancel and amend claims for condition of allowance.

Claims 13-14, 17-20 are cancelled.

The application has been amended as follows:

Claim 16, insert "wherein" prior to "the composition".

Claim 21, replace "the assay is validated using a positive control an antibody known to react with squalene" to -- further includes an antibody known to react with squalene as a positive control --

3. The following is an examiner's statement of reasons for allowance:

The instant invention recites a method of detecting squalene antibodies in a serum sample, the closest prior art is the reference of Asa (US6214566), however Asa's assay contains flaws with respect to the preparation of squalene antibodies. (See col. 9, example) Furthermore, Asa et al. do not provide positive control to validate its assay. The instant invention provides evidence generating a *monoclonal* antibody specific for squalenene. Accordingly, the recited invention is patentably distinct from Asa et al. reference.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Art Unit: 1641

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-282-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jacob Cheu  
Examiner  
Art Unit 1641



April 8, 2004



**LONG V. LE**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**

04/30/04